

Applicant : Bruce D. Gaynor et al.  
Serial No. : 08/833,838  
Filed : April 10, 1997  
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Claim Amendments:

Claims 1-53 (canceled)

Claim 54 (Currently amended): A method ~~for treating a subject having glomerulonephritis mediated by~~ of inhibiting binding of an anti-double stranded (ds)-DNA ~~antibodies that bind to the same epitope as an R4A antibody to glomeruli of renal tissue in a subject, wherein the anti-ds-DNA antibody binds to the same epitope as an R4A antibody,~~ the method comprising administering to said subject at least one peptide in an amount effective to bind to an ~~anti-double stranded ds-DNA~~ antibody in the subject, wherein said peptide comprises a D-amino acid sequence of X1-Trp-X1-Tyr-X2, wherein X1 represents Asp or Glu, and X2 represents Gly or Ser.

Claim 55 (Previously amended): The method according to Claim 54 wherein said peptide is 5-30 D-amino acids in length.

Claim 56 (Previously amended): The method according to Claim 54 wherein said peptide is 5-15 D-amino acids in length.

Claim 57 (Previously amended): The method according to Claim 54 wherein said peptide is 5-10 D-amino acids in length.

Claim 58 (Previously amended): The method according to Claim 54 wherein said peptide is 5 D-amino acids in length.

Claims 59-70 (canceled)

Claim 71 (Previously amended): The method according to Claim 54 wherein said peptide is 5-30 amino acids in length and comprises d-Asp-Trp-Glu-Tyr-Ser.

Claim 72 (Previously amended): The method according to Claim 71 wherein said peptide is 5-15 amino acids in length.

Claim 73 (Previously amended): The method according to Claim 71 wherein said peptide is 5-10 amino acids in length.

Claim 74 (Previously amended): The method according to Claim 71 wherein said

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peptide consists of d-Asp-Trp-Glu-Tyr-Ser.

Claim 75. (New): The method of claim 54, wherein the subject has glomerulonephritis.

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Specification Amendments:

Please amend the paragraph on page 1, lines 5-7 as follows:

This is a continuation-in-part of co-pending U.S. Application No. 08/531,832, filed September 20, 1995, now Patent No. 6,001,964, the contents of which are hereby incorporated by reference in their entirety.

Remarks

Claims 54-58 and 71-75 are pending in this case. Claim 54 has been amended and claim 75 added to more particularly point out and distinctly claim the invention. The amendment to claim 54 is supported in the specification at page 11, lines 28-page 12, line 1.

Rejection under 35 U.S.C. 112, first paragraph

All pending claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. It is asserted that undue experimentation would be required to practice the invention presented in the examined claims. Specifically, it is asserted that the claims are enabled for treating glomerulonephritis caused by the R4A antibody when the glomerulonephritis is induced at the time the peptide is added, but not generally for glomerulonephritis caused by anti-ds-DNA antibodies. Applicants respectfully request reconsideration and withdrawal of the rejection in light of the claim amendments and the following remarks.

The claims as amended are directed to a method of inhibiting binding of anti-ds-DNA antibodies that bind to the same epitope as the R4A antibody. As is clear in the specification, the R4A antibody binds to the peptides that are used in the claimed methods to inhibit the binding of the antibody. The description of the experimental data in the specification establishes that the peptides in the claims do inhibit binding of anti-

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ds-DNA antibodies to glomeruli, as claimed. Therefore, applicants assert that the claims are fully enabled.

Applicants also point out that antibodies that bind to the X1-Trp-X1-Tyr-X2 peptides are relevant to the etiology of systemic lupus erythematosus (SLE), since the peptide inhibited antibody binding to ds-DNA in sera of all SLE patients tested (n=10) in experiments reported in Sharma et al., 2003, Rheumatology 42:453-460 (copy enclosed). This further confirms the enablement of the claimed methods.

#### Conclusion

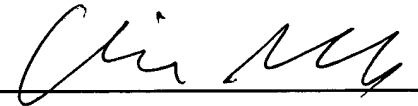
In light of the above discussion, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, first paragraph, and passage of the claims to allowance. Should there be any additional matters that prevent allowance of the claim, the Examiner is urged to contact the undersigned attorney.

No fee, other than the enclosed \$595.00 for the RCE filing and a two month extension or time, is deemed necessary in connection with this filing. If any additional fee is required to preserve the pendency of the subject application, authorization is hereby given to charge any such additional fee to Deposit Account No. 01-1785.

Respectfully submitted,

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